Navy Drug Screening Laboratory
Great Lakes, Illinois

Virtual Tour

LCDR Kevin L. Klette, MSC, USN
Commanding Officer

(Click above for Commanding Officer's Bio)

Virtual Tour Instructions

- Follow the slide presentation by clicking the return key.
- Certain Department slides have “virtual tour” links – to access them use the mouse to click the picture(s) on each departments slide. To return to the main presentation click the “Return to the Main Presentation” hyperlink.
- The presentation also includes several links to other web sites. To return to the virtual tour click the “back” button on the web browser.
- The last slide of the presentation contains a “End Presentation” link – click this to finish.

Mission, Vision and Guiding Principles

OUR MISSION:

To provide scientifically valid and legally defensible test results for selected drugs of abuse or drug metabolites in urine specimens to our customers in an accurate and efficient manner.

OUR VISION:

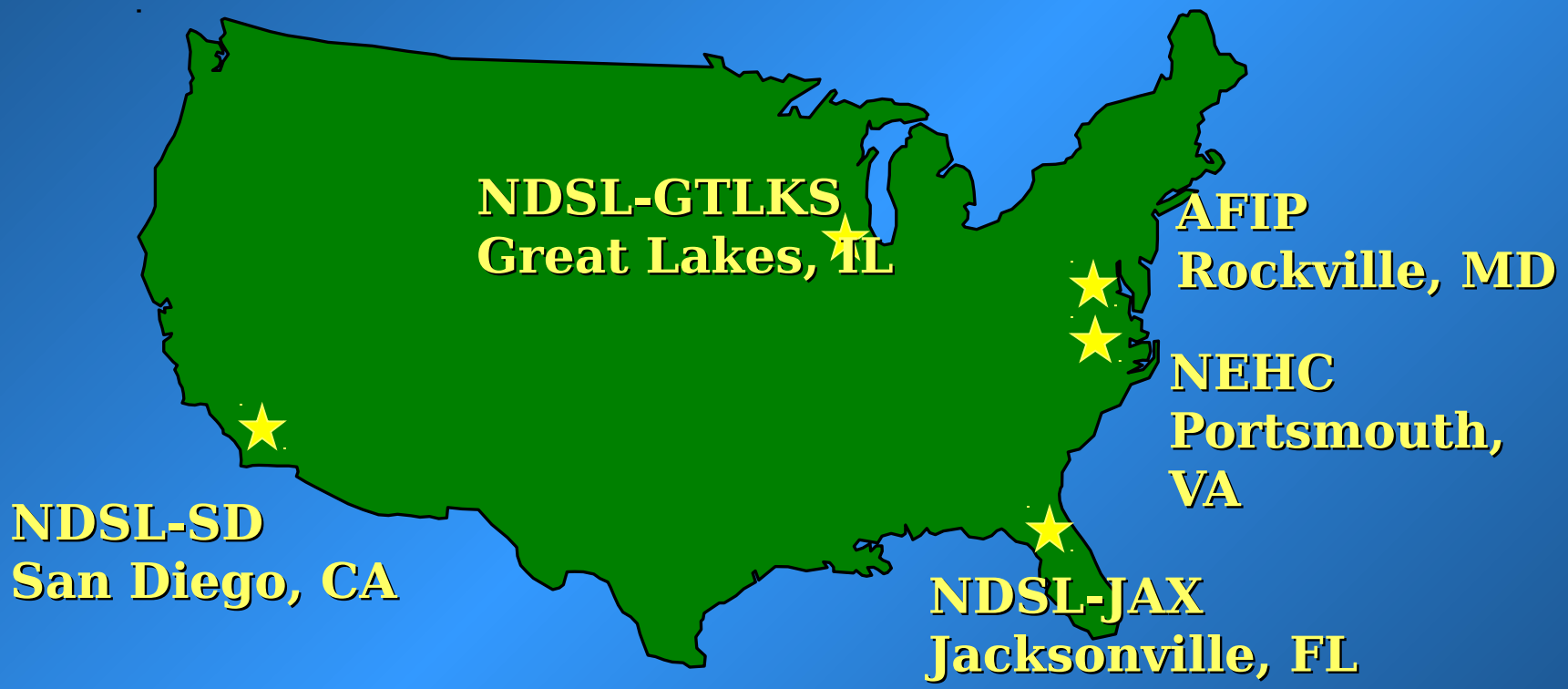
- **Dedication to quality customer service.**
- **Timely and accurate drug testing results.**
- **Expertise in forensic drug testing.**
- **Continuing efforts to be at the forefront of the drug testing industry.**
- **Ability to meet the ever-changing demands of drug deterrence through research and development.**

OUR GUIDING PRINCIPLES:

- **We will perform with the highest integrity; leading by example with honor, courage and commitment.**
- **We will strive for increase quality.**
- **We will advocate teamwork.**
- **We will encourage open communication up, down and across the chain of command.**
- **We will advocate stewardship.**
- **We will demand safety on the job and promote employee health.**

Navy Drug Screening Laboratory System

(Click on the Underlined Command to access the web site)



Operating under a common Standard Operating Procedures Manual.

Operational Authority

- DODINST 1010.16, OPNAVINST 5350.4C, and Urinalysis Program Coordinator (UPC) Handbook (OCT 2001).
  - Access the Drug and Alcohol Abuse Prevention Program home page at http://navdweb.spawar.navy.mil. Click on Publications. For the NDSP program, click on NDSP 5.1 icon.
- MCO P1700.24B MARINE CORPS PERSONAL SERVICES MANUAL
  - Access the Marine Corps home page (www.usmc.mil) click on Publications, Orders/Directives, View by SSIC, then SSIC 01000, Military Personnel. MCO can be found near the bottom of the list.
- Navy Drug Testing Program SOP
- To provide chemical analysis of urine specimens for the presence of controlled substances and illegal drugs under forensic conditions.

Testing Performed by Navy Drug Screening Laboratories

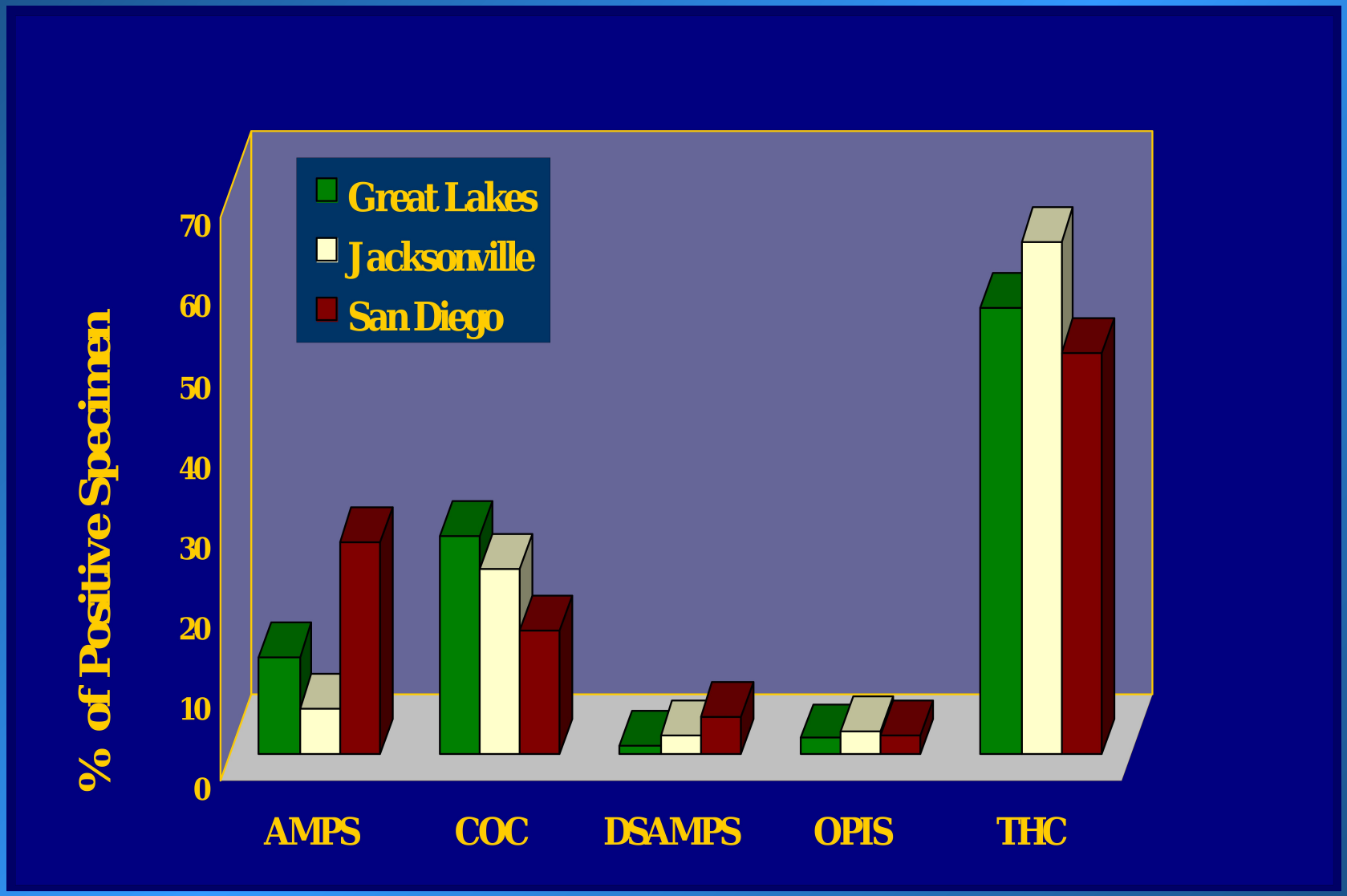
Routine Panel:

- Marijuana (THC metabolite)
- Cocaine (Benzoylecognine metabolite)
- Amphetamine & Methamphetamine
- Designer Amphetamines / Ecstasy (MDMA, MDA, MDEA)
- Heroin (6-Acetlymorphine metabolite)

Pulse Test Panel:

- Lysergic Acid Diethylamide (LSD)
- Opiates (Codeine, Morphine)
- Barbiturates
- Phencyclidine (PCP)
- Other (special requests)

Drug Use Trends – FY'03



The graph illustrates the positive sample by drug class between the three Navy Drug Screenin

Drug Testing Myths and Misconceptions

- **Labs use hair, saliva and blood: FALSE – The laboratories are only authorized to conduct drug testing using urine.**

- **The lab only conducts testing steroids and alcohol: FALSE – we do not test for steroids or alcohol. Authorization for steroid testing must come from PERS and will be conducted by UCLA:**
  - **Mr. Bill Flannery (901) 874-4400 (NAVY)**
  - **Contact Mr. Cruz Martinez (703) 784-9526 (MARINES)**

- **The laboratory selectively tests samples received from submitting commands: FALSE -- all samples are tested unless one of the following conditions exist:**
  - **Analysis would damage instrumentation**
    - **Other than urine (substituted)**
    - **Specimen is suspected of adulteration**
  - **Quantity not sufficient (QNS) for testing.**

Drug Testing Myths and Misconceptions

- **Passive inhalation of marijuana is a legitimate defense: FALSE – This claim is not supported by scientific evidence; impossible except in very extreme circumstances.**

- **Over-the-counter (OTC) medications will cause false positive for Methamphetamine: FALSE – this claim is not supported by scientific evidence. The laboratory employs testing procedures that differentiate between these types of drugs.**

- **Poppy seed ingestion may cause false positive for morphine: TRUE -- It is possible but extremely unlikely with new cutoffs.**

- **Vick's Inhaler causes false positive for methamphetamine: FALSE -- Not supported by scientific evidence.**

- **Lidocaine, novocaine, xylocaine cause false positive for cocaine: FALSE -- Not supported by scientific evidence, totally different molecules.**

When and How Many to Test

- **Random**
  - **Minimum requirement of 10 percent of all personnel assigned every month.**
  - **May test up to 40 percent at CO's discretion.**
  - **Weekend testing**

- **Unit Sweeps**
  - **Required to conduct one annual unit sweep**
  - **May conduct as many as five per year at CO's discretion.**

Chain of Custody

- **Proper chain of custody must be maintained at all times, beginning with specimen collection (DD form 2624).**
  - **WHO has custody of the urine sample? (Name Stamp and Signature)**
  - **WHAT purpose do they have custody of the sample? (Purpose).**
  - **WHEN do they have custody? (Date)**

Initial Testing Department: Accessioning Division

- Receives boxes of urine samples: Drop-off, U.S. Mail, UPS and FedEx
- Inspect box, bottles and chain of custody form - notes any problems or discrepancies
- Each bottle is assigned a random laboratory ID number
- Pours an aliquot of urine from bottle into test tube
- Only one bottle open at a time

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Cutoff Levels Definition

- **Cutoff Level: The concentration of drug (ng/mL) in urine that serves as an administrative breakpoint for calling a testing result positive or negative. Cutoff levels consider the following factors:**
  - **Analytical abilities of the instruments**
  - **Pharmacological factors**
  - **Non-abuse exposures**

What do the drug testing results mean?

- **Negative Test:**
  - The sample was either completely drug-free or the drug was present but below the DoD cutoff level by screening analysis.
- **Positive Test:**
  - The level of the drug found in the sample is greater than or equal to the DoD cutoff level by screening analysis (x2) and by confirmation analysis.
- Drug values below the cutoff are not reported. The command is told only that the sample was negative.

Initial Testing Department: Screening Division

- Quick/inexpensive immunoassay (IA) for separating samples with drug present at or above the cutoff concentration from those below the cutoff.
- IA gives only a “presumptive” identification of drug.
- “Presumptive positives” are rescreened, and if still positive are sent for confirmation.

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Confirmation Department

- **Definition: A second test by an alternate chemical method to positively identify a drug or metabolite.**
- **Gas chromatography - Mass Spectrometry**
- **100% Accurate**
  - **Ret. Time**
  - **Mol. Weight**
  - **Ion Ratios**

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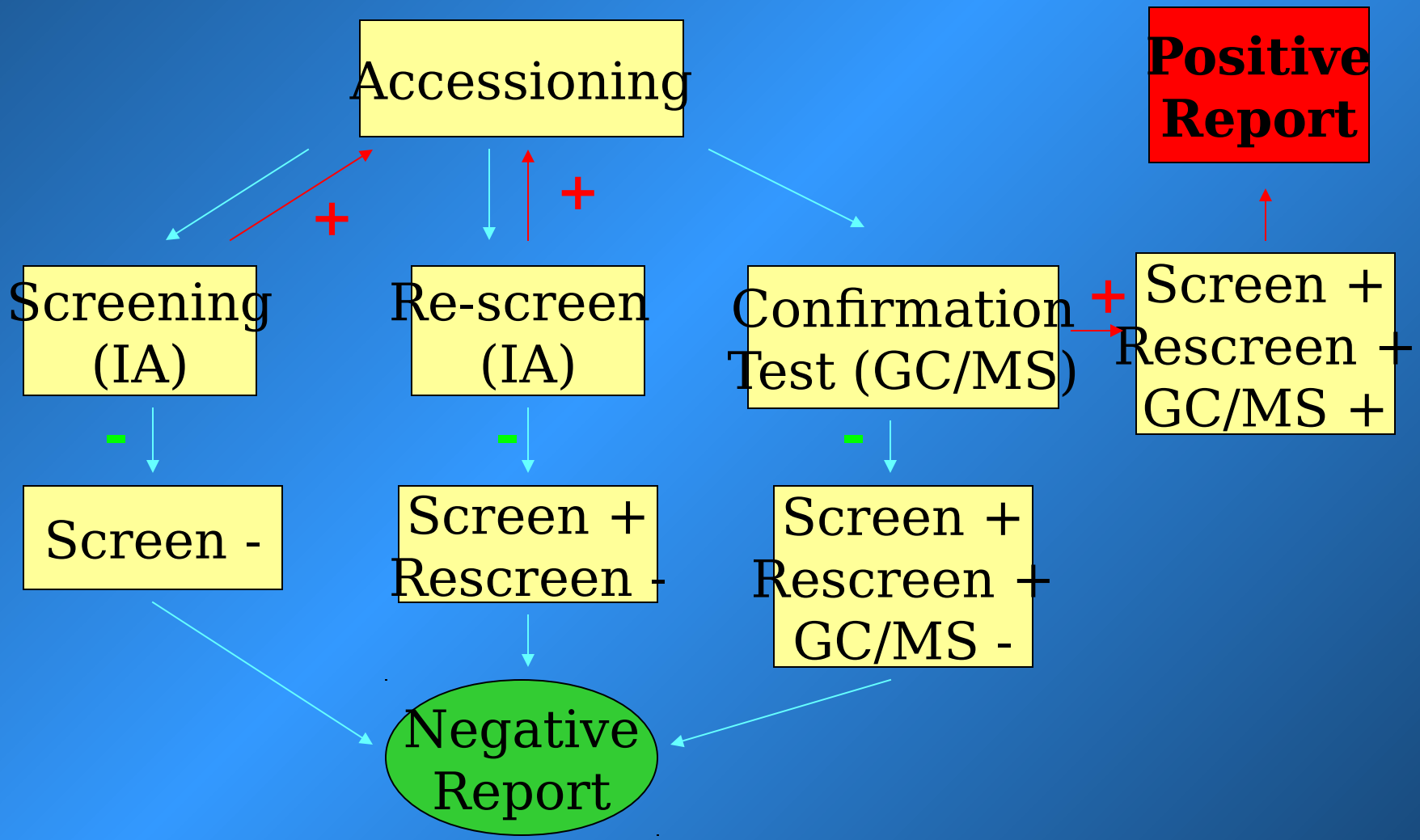
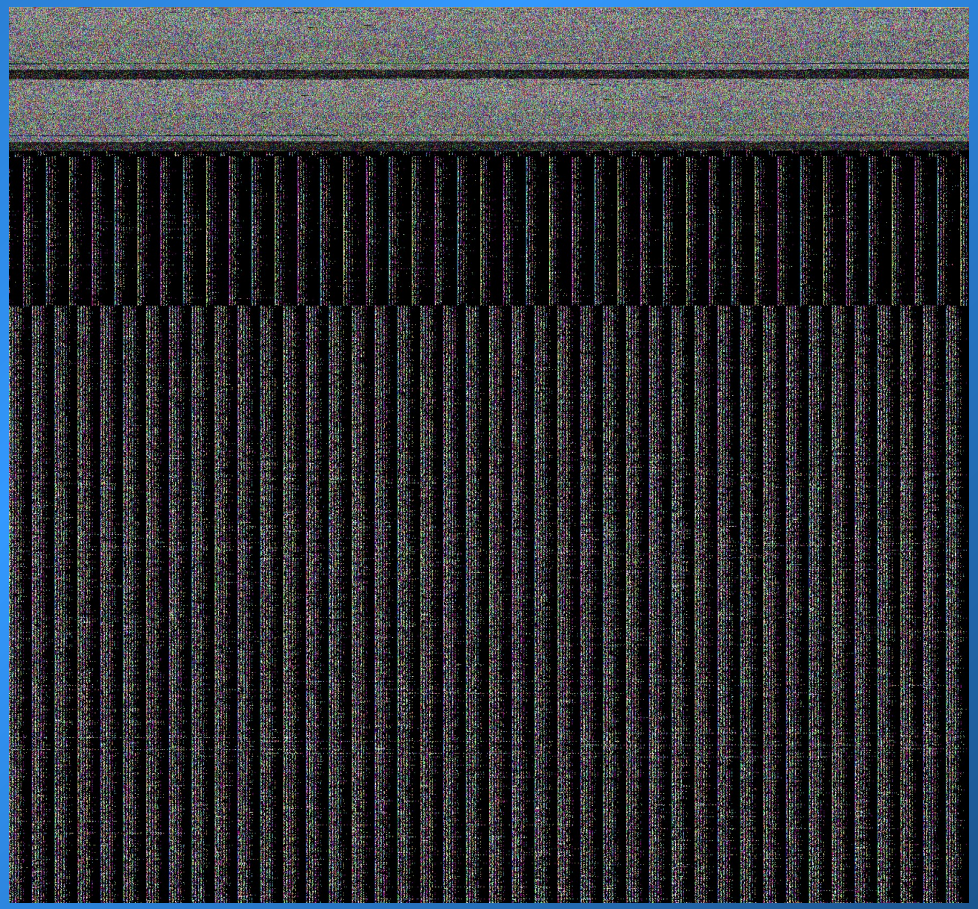
Specimen Handling

"Follow a specimen as it progresses through each stage



Quality Assurance / Quality Control Department

- **Monitors Internal QC Program:**
  - Preparation of Open Controls:
    - Screening & Confirmation
    - Known identity and level
  - Preparation of Blind Cotnrols
    - Screening & Confirmation
    - Identity and level unknown
- **Performs Initial Data Review:**
  - Provides initial LCO review for immunoassay data and QC review for GC/MS data.
- **Calibrates Pipetting Equipment**
- **Conducts Quality Assurance Audits**
- **Statistical Analysis**
  - Trend analysis for all controls
  - Monthly QA/QC report



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External Quality Assurance Program

- **Inspections**
  - 3 NEHC/year
  - 3 Greystone/year
    - 2 civilian forensic scientist
    - NavPers legal advisor
    - Armed Forces Institute of Pathology Rep
  - 1 DOD (every other year)

- **External QC (AFIP)**
  - Open Program
    - Screening and confirmation
  - Blind Program
    - Blind samples submitted via submitting commands
    - 1981-2003
      44,000 blind negatives submitted, none tested positive

Failsafe Procedures

- All three tests (initial screen, rescreen, and confirmation) must be positive before a positive result is reported
- Extensive review process prior to reporting
  - Technician
  - Quality Control
  - Initial Laboratory Certifying Official
  - Final Laboratory Certifying Official
  - Administrative Forms Review
  - Certifying Official
- Compartmentalization of laboratory

Support Services Department

Click Picture for Virtual Tour

- **Messages to Fleet and FMF on all testing results.**
- **Documentation Packets for Legal/Admin Processes.**
- **Expert Witnesses for Legal/Admin Proceedings.**
- **Technical consultation**

Technical Review Division

***Legal Support*:**

- **Contact the experts at your Navy Drug Screening Laboratory to answer any questions concerning positive results**
- **They represent science - no victim to avenge, no guilty or innocent person to ruin or save - they will bear witness within the limits of science**

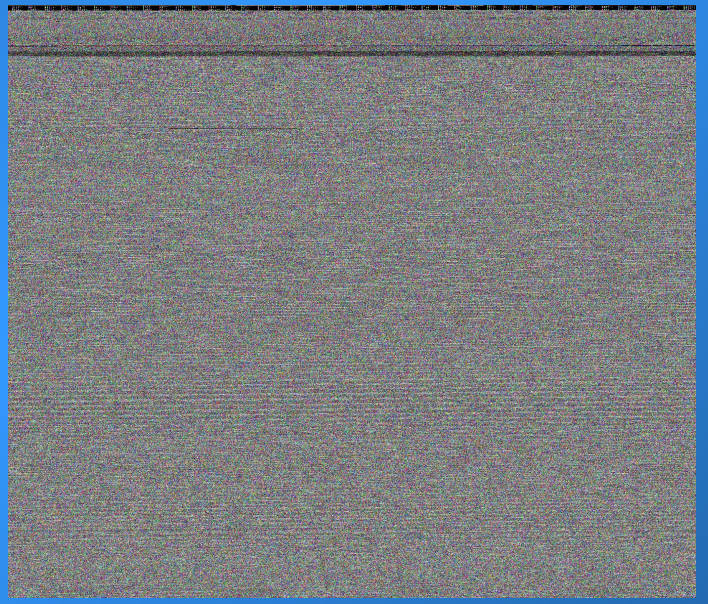
***Technical / MRO Support*:**

- **All reported positive results for amphetamines, barbiturates, and opiates require medical review by NDSL after checking the medical record for prescription medications before it is ruled a drug incident.**

Data Review:

- Military Biochemists/Toxicologists and civilian chemists review all data sets for accuracy, forensic integrity and legal

Resources and Information Systems Departments



Resources Department

The Resources Department has the following responsibilities:

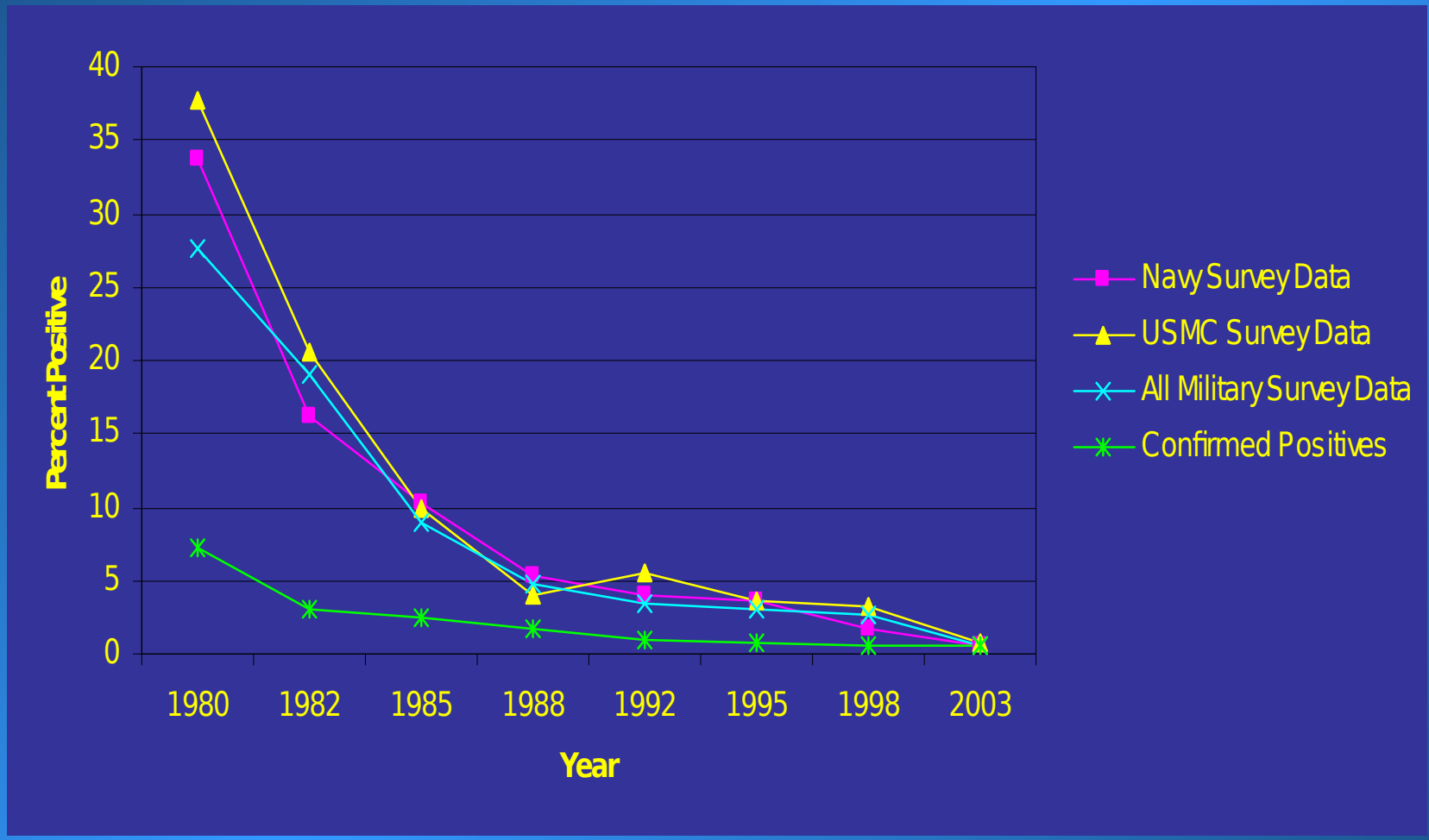
- **Financial / Budget**
- **Time and Attendance**
- **Payroll**
- **Facilities Maintenance**
- **Supply**
- **Custodial**
- **Medical Waste Disposal**
- **Travel**

Information Systems Department

The Information Systems Department provides the following functions to the laboratory:

- **Laboratory Information Systems (LIMS) maintenance**
- **Work station , and equipment technical support**
- **DMS and data transmission support**
- **Research and Development**
- **Database back-up / archiving**
- **Monthly report generation**

Navy Drug Testing Program: Success as a Drug Use Deterrent



This graph illustrates data collected from two separate sources; the first is self-reported survey data and the second is laboratory confirmed positive data. The data shows a decrease in both self reported and confirmed drug use since the inception of the Navy Drug Testing Program.

• This Concludes the Virtual Tour of the Navy Drug Screening Laboratory -- Great Lakes, Illinois. Should you have further questions regarding the Navy Drug Testing Program, legal, technical or medical review officer support – the contact information for the laboratory is listed below:

Commanding Officer: LCDR Kevin Klette (847) 688 – 2045 x 21
Executive Officer: LT Robert Welton (847) 688 – 2045 x19
Production Manager: LT Cynthia Kukoski (847) 688 – 2045 x 22
Technical Director: Dr. J. Jacob Snyder (847) 688 -2045 x 13
Assistant Technical Director: LT Matthew Jamerson (847) 688 – 2045 x 15
Training Officer: LTJG Aaron Kettle (847) 688 – 2045 x 42
Director for Administration: Ms. Linda Morgret (847) 688 – 2045 x12
Command Secretary: Ms. Tina Robin (847) 688 – 2045 x12

• Click on the link below for questions regarding collection, steroid testing, NDSP or for Urinalysis Program Coordinator information.

http://navdweb.spawar.navy.mil

END PRESENTATION

Virtual Tour - Accessioning

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Accessioning receives specimens from a variety of sources including U.S. Mail, Federal Express, and Courier. Regardless of the source all samples are processed first by Accessioning.

Each specimen box is checked to ensure that the packaging and specimen bottles are intact and show no evidence of tampering.

After initial processing, samples are "batched" into groups of 100. Each batch then undergoes a series of verification steps in which information on the Chain of Custody is verified against the information on the bottle.

Upon completion of the verification process each sample is poured for immunoassay testing. Each sample is actually poured and tested twice for immunoassay analysis.

Samples screening positive by immunoassay are considered "presumptive" positives, and are poured a third time for analysis by Gas Chromatography / Mass Spectrometry (GC/MS).

Click on above picture to access the NDSL Great Lakes Discrepancy Code List.

Virtual Tour - Screening

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NDSL Great Lakes uses state of the art automated Immunoassay analyzers to conduct the first two stages of testing. Shown above is the Hitachi DDP configuration that serves as the labs main production instrument.

The lab also uses a stand alone Hitachi P2 module – this instrument functions as a back up to the DDP, the primary instrument for re-immunoassay analysis as well as the research and development instrument.

Both instruments use commercially available reagent kits to screen for drugs of abuse. The instruments are used to screen the small number of presumptive positive from the large number of negative specimens.

The Hitachi systems combine modern technology and automation with high throughput capabilities that allow the laboratory to meet the DoD and customer turnaround time requirements.

Virtual Tour - Confirmation

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The confirmation department is the last stop for all presumptive positives samples. This section is responsible for chemically and physically extracting drugs of abuse or their metabolites from urine prior to analysis by Gas Chromatography / Mass Spectrometry (GC/MS). Additionally, the section is currently developing Fast GC/MS methods to decrease the current run time for marijuana, amphetamines and cocaine metabolites. Furthermore, the department will also implement Liquid Chromatography / Mass Spectrometry (LC/MS) for use in the detection of LSD metabolites.

The laboratory utilizes 13 state of the art Gas Chromatograph / Mass Spectrometers to identify and quantify drugs of abuse or their metabolites with 100% accuracy.

Virtual Tour - Support Services

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One of the main functions of the Support Services Department is to ensure that all data received from submitting commands is entered into the laboratory information system with 100% accuracy. The department achieves this goal through the use of full page scanning technology. This technology allows a full administrative batch of 100 samples to be entered into the data base in less than 15 minutes. The combination of the automated technology and properly bar coded forms has led to a significant decrease in the

Other functions of the department include:

- **Administrative review of data sets prior to military message preparation.**
- **Preparation of litigation packages for use by the laboratory expert witnesses and the Navy legal community**
- **Military message generation and transmission via Defense Messaging System (DMS).**
- **Daily electronic reporting to USMEPCOM.**
- **Processing Command re-test requests.**

The Support Services department also has the task of maintaining the laboratory data archives. All data sets produced by the testing process are stored in the archives for three years prior to final disposal.

Virtual Tour – QA/QC

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Standards and Controls

• Quality Assurance / Quality Control is the hub and one of the most critical functions is the preparation of laboratory standards and controls. Annually the department prepares, certifies and tracks the performance of thousands of standards and controls. Each control solutions used (immunoassay and GC/MS) undergoes a rigorous certification process prior to its use in the testing process.

• The department also tracks the performance of each control solution over the course of its life time to ensure that each standard is performing within the acceptable ranges.

• An important part of the QA/QC function is the maintenance of the laboratory's internal blind and open control program. QA/QC's main function is to ensure that the laboratory has an adequate daily supply of these controls to meet production requirements as well as to ensure that each control is testing appropriately.

• The department must also ensure that all pipetting equipment

Data Review

• An equally important function of QA/QC is data review. The department is the first stop for all data generated within the laboratory. QA/QC technicians review each data set to ensure that each blind and open standard and control has tested appropriately.

• QA/QC also conducts monthly Quality Assurance audits for all laboratory sections. Data generated by these audits are used for continuous process improvement.

• This section also provides the laboratory with statistical and